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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,499	07/25/2003	John A. Kink	OPHD-08311	3266

7590 10/04/2006  
MEDLEN & CARROLL, LLP  
Suite 350  
101 Howard Street  
San Francisco, CA 94105

EXAMINER
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XIE, XIAOZHEN

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/627,499	KINK ET AL.	
	Examiner	Art Unit	
	Xiaozhen Xie	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 59-66 and 68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 59-65 is/are allowed.
- 6) ☒ Claim(s) 66 and 68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendment of the claims received on 10 July 2006 has been entered. The terminal disclaimer filed on 10 July 2006 has been entered.

Claim 67 has been cancelled. Claims 59-66 and 68 are pending and under examination. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Claim Objections/Rejections Withdrawn***

The rejection of claims 59, 60, 62, 64 and 65 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,663,864 B1 in view of Eigler et al., and further in view of Woolley and Landon, is withdrawn in response to Applicant's filing of the terminal disclaimer.

The rejection of claims 59-65 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,395,273 B1 in view of Eigler et al., and further in view of Woolley and Landon, is withdrawn in response to Applicant's filing of the terminal disclaimer.

The rejection of claims 66-68 under 35 U.S.C. 103(a) as being unpatentable over Woolley and Landon, in view of Otto et al., is withdrawn in response to Applicant's argument that the Woolley and Landon reference does not teach purifying antibodies using PEG.

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The rejection of claim 59 under 35 U.S.C. §112, second paragraph, as being indefinite for omitting essential steps of the method, is withdrawn in response to Applicant's amendment of the claim.

The objections of claims 59 and 64 for informalities are withdrawn in response to Applicant's amendment of the claims.

### ***New Grounds of Rejections***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 66 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woolley and Landon (J. Immunol. Methods, 1995, Vol. 178, pp. 253-265), in view of Polson et al. (Immunol. Commun., 1980, 9(5):475-493), and further in view of Otto et al. (Clin. Diagn. Lab. Immunol., 1997, July, Vol. 4(4), pp. 487-90).

Woolley teaches a method of preparing antibodies directed to human interleukin-6 (IL-6) from chicken egg yolk. Woolley detailed the procedure of purifying the anti-IL-6 antibodies from the egg yolk including collecting chicken eggs which comprise the antibodies, separating egg yolk from egg white, and purifying the antibodies from the egg yolk (pp. 255, in Materials and Methods section). Woolley, however, does not teach using polyethylene glycol for purifying antibodies from egg yolk, nor preparing antibodies directed to human TNF- $\alpha$ . Polson teaches isolating antibodies from chicken

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yolks by the use of polyethylene glycol (PEG). Polson teaches that a concentration of 3.5% of the polymer caused the lipids and vitellin to separate, and the IgY was then precipitated with 12% PEG (see Abstract). Otto further teaches that antibodies directed to feline TNF or the synthetic peptides based on the feline TNF sequence can be raised in chicken, and these antibodies specifically bind to a recombinant human TNF (pp. 487, Abstract and pp. 489, Table 2).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to modify the teachings of Woolley and Polson regarding purification of antibodies from chicken egg yolk by using the disclosure of Otto to prepare antibodies directed to human TNF- $\alpha$  from chicken egg yolk. One of ordinary skill in the art would have been motivated to combine the teachings, because Woolley teaches a method of preparing antibodies against IL-6, a closely related cytokine to TNF- $\alpha$ , from chicken egg yolk, Polson teaches the use of PEG for the purification process, and Otto teaches that chicken can produce polyclonal antibodies directed to feline TNF, and that the resulting antibodies bind to human TNF. Therefore, the combined teachings provide a reasonable expectation of successfully making chicken egg yolk-derived anti-huTNF- $\alpha$  antibodies.

### ***Conclusion***

CLAIMS 59-65 ARE ALLOWABLE.

CLAIMS 66 AND 68 ARE REJECTED.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

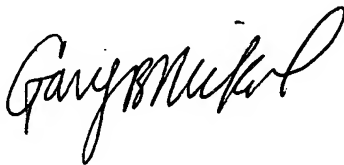
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.  
September 20, 2006

A handwritten signature in black ink, appearing to read "Gary B. Nickol". The signature is fluid and cursive, with the first name "Gary" and last name "Nickol" clearly distinguishable.

GARY B. NICKOL, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600